REMARKS

The Specification has been amended to include SEQ ID number identifiers and to correctly describe Figures 5 and 7. Claims 1 and 2 are amended to remedy indefinite language and to address rejections under 35 U.S.C. § 112 and 35 U.S.C. § 102 as discussed below. No new matter has been introduced by this amendment. The following addresses the substance of the Office Action.

Priority

The patent office has taken the position that U.S. provisional application No. 60/402,055, filed August 9, 2002 and Australian provisional application no. 2002951579, filed August 22, 2002 do not provide adequate support or enablement under 35 U.S.C. §112 for Claim 1 that formerly read: "An isolated nucleic acid molecule comprising a sequence of nucleotides encoding or complementary to a sequence encoding a mammalian transcription factor comprising an amino acid sequence having at least 75% identity to SEQ ID NO:8 (human SOM) or SEQ ID NO:16 (murine SOM) after optimal alignment." In addition, the Examiner stated that the prior filed applications fail to provide support or enablement for Claim 2 language that recited high stringency conditions which are 0.1 x SSC, 0.1% w/v SDS at 65°C.

Applicants wish the Examiner to note that the instant application and the priority applications are virtually identical. Table 1 lists identical supporting text from each of the two priority applications and the international application, currently in National Phase:

Table 1. Identical supporting text from each of the two priority applications and the international application, currently in National Phase.

Supporting Text	**Application No.**	**Citation**
Preferred percentage amino acid similarity levels include… at least about 95%...similarity.	60/402,055	p. 15: 15, 23
	AU 2002951579	p. 15: 16, 25
	PCT/AU2003/001006	p. 19: 17, 26
The term "similarity" as used herein includes exact identity between compared sequences at the nucleotide or amino acid level.	60/402,055	p. 17:9-10
	AU 2002951579	p. 17: 10-11
	PCT/AU2003/001006	p. 21:11-12
In a particularly preferred embodiment, nucleotide and sequence comparisons are made at the level of identity rather than similarity.	60/402,055	p.17:15-16
	AU 2002951579	p.17:16-18
	PCT/AU2003/001006	p.21:17-19
…high stringency is 0.1 x SSC buffer, 0.1% w/v SDS at a temperature of at least 65°C.	60/402,055	p. 20:7-8
	AU 2002951579	p. 20:7-8
	PCT/AU2003/001006	p. 24:10-11

Claim 1 has been amended herein to be significantly narrower in scope than at least about 75% similarity, reciting "An isolated nucleic acid molecule comprising a sequence of nucleotides encoding a mammalian transcription factor comprising an amino acid sequence having at least 95% identity to SEQ ID NO:8". As seen in the table above, page 21, lines 11-12 of the specification defines the term "similarity" as including exact identity between compared sequences at the nucleotide or amino acid level, and page 21, lines 17-19 indicates that the comparisons can be made by "level of identity rather than similarity." This same language appears in the two priority applications. The support for "95% identity" is also shown in the table in both the present application as well as the two priority applications. Thus, it is clear that the claims as presently amended are fully supported by both the present application as well as the priotiy applications.

Regarding claim 2, the three applications provide identical support for high stringency conditions as 0.1x SSC buffer, 0.1% w/v SDS at a temperature of at least 65°C, including at 65°C. Thus, it is quite clear that claims 1 and 2 are entitled to the priority of the filing date of U.S. Provisional Application No. 60/402,055 (*i.e.*, August 9, 2002).

Sequence compliance

The specification failed to provide sequence identifiers with sequences set forth in Figures 1A, 1C and 3A. Applicants have resolved this issue by amending the Brief Description of the Drawings to include sequence identifiers. The previously submitted Sequence Listing did not contain sequences for Figure 1C and 3A. Thus, a substitute sequence listing is submitted herewith that contains all of the referenced SEQ ID numbers, including newly referenced SEQ ID Numbers 47-50.

Drawings

The drawings were objected to under 37 C.F.R. § 1.83 because they failed to show Figures 5E and 5F as described in the Specification. Under the header "Brief Description of the Figures, the description of Figure 5 formerly included descriptions 5E and 5F, which should have been associated Figure 7 to describe Figure 7E and 7F. The Specification is amended to correct the error. In addition, reference to Fig. 5E and F under Example 16 is amended to correctly refer to Fig. 7E and 7F. In conclusion, the drawings were correct as submitted, but the Specification has been amended to correctly refer to the drawings.

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 1-2 and 3-6 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The phrase "optimal alignment" was unclear. Thus the Applicants have amended claim 1 to remove the phrase.

In addition, claims 1 and 2 were found to be indefinite because they recited both narrow and broad terms (e.g., SEQ ID NO: 8 (human SOM)). Claims 1 and 2 are amended to only recite the narrow SEQ ID number limitations.

Claim 2 was found to be vague and indefinite in that the metes and bounds of "high stringency conditions" are unclear. Claim 2 is amended to remove the phrase "high stringency conditions" and to specifically recite conditions of 0.1X SSC, 0.1% w/v SDS at 65°C.

Claim 2 was also found to be vague and indefinite in that the metes and bounds of a "complementary form" of a nucleic acid which is capable of hybridizing to SEQ ID NO: 7 or SEQ ID NO: 15 are unclear. Claim 2 is amended to recite "a nucleotide sequence which hybridizes to a full complementary sequence of SEQ ID NO: 7 or SEQ ID NO: 15. Thus, removal of the rejection is requested.

Rejection under 35 U.S.C. §112, First Paragraph

Claim 2 was rejected as failing to comply with the written description requirement. In particular, the Examiner stated that the Specification as originally filed does not provide support for the invention as now claimed: "...high stringency conditions (0.1X SSC, 0.1% w/v SDS at 65°C)." The Applicants note that high stringency is defined in the Specification on page 24, lines 10-11 as 0.1x SSC, 0.1% w/v SDS at a temperature of at least 65°C. Amended claim 2 states "under conditions of 0.1X SSC, 0.1% w/v SDS at 65°C". With regard to claim scope, the phrase "at 65°C" refers to the least stringent condition within the scope of the phrase "at a temperature of at least 65°C". Thus, the recited conditions including "at 65°C" qualify as high stringency as defined by the Specification, the term "high stringency" is no longer included in amended claim 2. The applicants respectfully request removal of the rejection.

Claims 1-2 were rejected under 35 U.S.C. § 112, first paragraph based on allegation that the Specification, while being enabling for an isolated nucleic acid encoding SEQ ID NO: 8 or SEQ ID NO: 16, does not reasonably provide enablement for a nucleic acid encoding or

complementary to a mammalian transcription factor (i.e., any MGH homolog) comprising any polypeptide with at least 75% identity to SEQ ID NO: 8 or SEQ ID NO: 16. Claim 1 has been amended to recite "...having at least 95% identity to SEQ ID NO: 8", to define nucleic acid sequences encoding or complementary to sequences that encode polypeptides having at least 95% identity with human SOM. Since isolated nucleic acids described by this narrow definition are enabled by the Specification, the Applicants respectfully request removal of the enablement rejection.

Claims 1-2 were also rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner alleged that the claims encompassed any nucleic acid sequence comprising at least two "nucleobases" which can precisely pair with any sequence present in a nucleic acid which encodes a homolog of M-GRH comprising an amino acid sequence having at least 75% identity to human or murine *som* after optimal alignment, and that the encompassed sequences need not encode a transcription factor at all. To resolve this issue, Amended claim 1 does not contain the phrase "or complementary to a sequence encoding" and claim 2 specifies a nucleotide sequence which hybridizes to a fully complementary sequence of SEQ ID NO: 7 or SEQ ID NO: 15.

On pages 18-19 of the Office Action, the Examiner alleged that a written description was lacking for a set of genes which encode proteins that have at least 75% identity to any human SOM or any murine SOM. As stated above, claim 1 has been amended to recite "...having at least 95% identity to SEQ ID NO: 8", to define nucleic acid sequences encoding or complementary to sequences that encode polypeptides having at least 95% identity with human SOM. Dependent claim 2 recites "a nucleotide sequence selected from the group consisting of SEQ ID NO: 7, SEQ ID NO: 15, and a nucleotide sequence which hybridizes to a full complementary sequence of SEQ ID NO: 7 or SEQ ID NO: 15 under conditions of 0.1X SSC, 0.1% w/v SDS at 65°C". The Written Description Guidelines of MPEP 2163 et seq. and the accompanying examples support the written description support for the present claims reciting 95% identity. Thus the claims are in compliance with the written description requirement of 35 U.S.C. § 112, first paragraph since they are narrowly directed to nucleic acid molecules encoding SEQ ID NO: 7 or SEQ ID NO: 15, and closely related nucleic acids.

Rejection under 35 U.S.C. § 102(a)

Claims 1-2 are rejected under 35 U.S.C. § 102(a) as being anticipated by Ting et al. 2003 *Biochem J.* **370**:953-962. However, Ting et al. can not qualify as a 35 U.S.C. § 102(a) reference since the priority application 60/402,055, filed August 9, 2002 (see discussion above regarding qualification as a priority document) predates the publication of Ting et al. 2003. Thus, the Applicants respectfully request removal of this rejection.

Rejection under 35 U.S.C. § 102(b)

Claims 1-2 are rejected under 35 U.S.C. § 102(b) as being anticipated by BM460207 (1999). Exhibit B of the Office Action shows an alignment of BM460207 and SEQ ID NO: 7. Nevertheless, Claim 1 is directed to "An isolated nucleic acid molecule comprising a sequence of nucleotides encoding a mammalian transcription factor comprising an amino acid sequence having at least 95% identity to SEQ ID NO: 8". SEQ ID NO: 8 is a 607 amino acid long protein sequence. Due to the degeneracy of the genetic code, multiple nucleotide sequences can encode an amino acid sequence having at least 95% identity to SEQ ID NO: 8, but the nucleotide sequence of BM460207 does not meet the definition. Referring to Exhibit 1, BM460207 is an EST sequence that, when translated in Frame 1, only encodes a 163 amino acid long region that aligns with SEQ ID NO: 8. Even if the entire 163 region of alignment was identical to SEQ the corresponding region of SEQ ID NO: 8, the sequences would only have 26.8% identity to SEQ ID NO: 8. Thus, BM460207 does not anticipate claim 1 and removal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

CONCLUSION

In view of Applicants' amendments to the Specification, the Substitute Sequence Listing, the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 13 Aug. 2007

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